DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 26, 2015

Vector Corporation LLC
c/o Ms. Laurie Lewandowski
Honkanen Consulting, Inc.
738 Saddle Wood Drive
Eagan, MN 55123

Re: K143652
Trade/Device Name: Vector PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: January 30, 2015
Received: February 2, 2015

Dear Ms. Lewandowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K143652

Device Name
Vector™ PTA Balloon Dilatation Catheter

Indications for Use *(Describe)*
The Vector™ PTA Balloon Dilatation Catheter is recommended for Percutaneous Transluminal Angioplasty (PTA) of the femoral, iliac, popliteal, and renal arteries and for the treatment of obstructive lesions of native or synthetic arterio-venous dialysis fistulae.

The Vector Catheter is not indicated for use in the coronary arteries or for placement of or post dilation of stents.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Vector Corporation

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Device Name
Trade Name: Vector™
Common Name: Percutaneous Catheter
Classification Name: Percutaneous Catheter
Classification: II
Product Code: LIT
Regulation Number: 21 CFR 870.1250

Predicate Device
The device is substantially equivalent to the r4 Vascular, Inc. Vector$^{4™}$ PTA Balloon Dilatation Catheter (K131329).

Indications for Use/Intended Use
The Vector™ PTA Balloon Dilatation Catheter is recommended for Percutaneous Transluminal Angioplasty (PTA) of the femoral, iliac, popliteal, and renal arteries and for the treatment of obstructive lesions of native or synthetic arterio-venous dialysis fistulae.

The Vector™ Catheter is not indicated for use in the coronary arteries or for placement of or post dilatation of stents.

Device Description

The Vector™ PTA Balloon Dilatation Catheter is a high pressure, non-compliant balloon catheter. It is a coaxial dual lumen over-the-wire balloon dilatation catheter. The central lumen accommodates guide wires up to the 0.035 inches in diameter while the outer lumen is the inflation lumen for the balloon.

The balloon is a high pressure composite balloon with radio-opaque marker bands to help visualize the balloon placement within the vasculature during both placement and inflation. The balloon's rated burst pressure is 30 atm.

Technological Characteristics

The Vector™ PTA Balloon Dilatation Catheter was cleared under K131329. The fundamental scientific technology and technological characteristics for the Vector™ PTA Balloon Catheter remain the same as Vector^{4}™ PTA Balloon Dilatation Catheter.

Vector™ is a coaxial dual lumen over-the-wire balloon dilatation catheter. The central lumen accommodates guide wires up to 0.035 inches in diameter while the outer lumen is the inflation lumen for the balloon. The catheter includes an atraumatic tip to ease advancement of the catheter to and through the stenosis.

The balloon is a high pressure, Parylene coated, composite balloon with marker bands located at the proximal and distal end of the balloon working length and at the distal tip to help visualize placement within the lesion or stenosis. The balloon's rated burst pressure is 30 atm.

The catheter is supplied sterile and non-pyrogenic. Different balloon sizes (5 mm to 10 mm) and catheter lengths (50 to 135 cm) are available. The proximal end of the catheter contains a hub with two female luer locks.

The device is compatible with 6-7F introducers. The introducer compatibility for each device size is listed on the device label. The materials used in the construction are biocompatible and not made with natural rubber latex.

The modifications to the Vector™ PTA Balloon Dilatation Catheter are as follows.

1) Removal of radiopaque coating, $BaSO_4$ tip doping and addition of marker bands
2) Angled the balloon fibers and modified the fiber denier
3) Updates to the IFU for company name, product name, use of contrast
4) Increased flow for reduced inflation / deflation times
5) Increased product robustness for balloon bonds and reduction in introducer withdrawal force
6) The 6 Fr balloon protector ID was increased slightly.

There are no changes in the balloon catheter dimensions or significant changes in weight with these modifications.

Performance Data

Based on the risk analysis of the modified device, and testing was conducted on the modified Vector™ PTA Balloon Dilatation Catheter. The testing performed on the modified devices was:

Rated Burst Pressure, Balloon Compliance, Balloon Diameter Sizing, Inflation/deflation times, Repeat Inflation, Removal/Refold & Reuse, Flexibility / Kink, Crossing Profile, Balloon Protector Removal, Guide wire/Introducer Compatibility, Tensile Strength, Visibility under Fluoro-imaging, Torque Strength and Catheter Leak.

All devices met the performance specifications.

The device is sterilized by ethylene oxide to an SAL 10^{-6} level and the device is biocompatible meeting the requirements of ISO 10993-1.

The bench testing demonstrated that the device meets specifications indicating that the device is as safe and effective as the predicate device.

Substantial Equivalence

The modified Vector™ PTA Balloon Catheter is substantially equivalent to the Vector4™ PTA catheter (K131329). They have the identical intended use, and treat the same target population. Both devices are intended to treat peripheral arteries. The manner in accessing and treating lesions in all these arteries is identical. The devices are similar in design with changes as described.

Conclusion

The modified Vector™ PTA Balloon Catheters and the predicate Vector4™ PTA Balloon Catheters have identical intended use and similar technological characteristics and are therefore substantially equivalent. Bench testing of the Vector™ PTA Balloon Dilatation Catheters demonstrated that all product specifications were met. These tests demonstrate that the Vector™ PTA Balloon Dilatation Catheters are as safe and effective as the predicate device.